

REMARKS**BEST AVAILABLE COPY**

Each of claims 1-22 stands finally rejected by the Examiner in the Official Action of May 14, 2001. There are three independent claims pending in this application, claims 1, 2 and 16. Claims 1 and 16 are composition of matter claims that have been amended to read as above. Claim 2 is a method of manufacture claim that has not been amended through this paper.

Claims 1-6 and 11-20 were rejected under § 102(b) as anticipated by the '051 patent; claims 1-8 and 11-22 were further rejected under § 103(a) as obvious in view of the '051 patent; and claims 9 and 10 were rejected under § 103(a) as obvious in view of the '051 patent, further in view of the Bonefield reference. Applicants respectfully traverse each of these rejections for the reasons expressed below and request their withdrawal by the Examiner.

As amended, each of claims 1 and 16 now require that the polymeric reinforcing component is mixed with the polymeric matrix component, and that the bioceramic or bioglass reinforcing component is mixed with the polymeric matrix component. Likewise, method claim 2 in its unamended form contains the same requirements.¹

¹ Claim 2 was not amended in this paper. For ease of reference, the language of pending claim 2 is reproduced below, with emphasis added to show the mixture steps:

2. A method of manufacturing a biodegradable composite according to claim 1, comprising the steps of:
 - a) selecting at least one first polymer for the matrix;
 - b) selecting at least one bioceramic material, bioglass material or mixture thereof for use as the bioceramic or bioglass reinforcing component;
 - c) *mixing said first polymer and said bioceramic or bioglass reinforcing component together to form a mixture;*
 - d) *selecting at least one second polymer in a fiber form for the resorbable polymeric reinforcing component;*
 - e) *placing said second polymer into a desired formation;*
 - f) *combining said mixture of step (c) and said formation of step (e) to yield a second mixture; and*
 - g) subjecting the second mixture of step (f) to heat or pressure.

In sharp contrast, the '051 patent recites *a layered material* wherein a bioceramic piece (1) is layered on top of material component (2), which may also contain a ceramic material. Thus, the biocomposite material of the '051 patent lacks the requirement of each of independent claims 1, 2 and 16 (and, therefore, the claims dependent therefrom) that the reinforcement elements are mixed with the polymeric matrix, as are the bioceramic or bioglass components.

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Accordingly, Applicants' respectfully submit that the rejection of claims 1-6 and 11-20 as anticipated by the '051 patent should be withdrawn, as should the rejection of claims 1-8 and 11-22 as obvious over the '051 patent and the rejection of claims 9-10 as obvious over the combination of the '051 patent and Bonefield. Indeed, there is no teaching or suggestion present in the cited prior art to mix the polymeric reinforcing component, the bioceramic or bioglass component and the polymeric matrix to yield the composite material of Applicants' invention, having the stated advantages (including ductility). Thus, one of ordinary skill in the art would not have been motivated to alter these references to reach Applicants' claimed invention.

For all of these reasons, it is respectfully submitted that the subject application is now in condition for immediate allowance. A Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

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MARKED-UP VERSION OF AMENDED CLAIMS

1. (Four Times Amended) A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component as a large scale reinforcing element, wherein said polymeric reinforcing component is mixed with said matrix component, and iii) at least one bioceramic or bioglass reinforcing component as a smaller scale reinforcing element mixed with said matrix component, said bioceramic or bioglass reinforcing component being a bony ongrowth agent having coarse particles, wherein said composite material is ductile.

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16. (Three Times Amended) A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component in fiber form, wherein said polymeric reinforcing component is mixed with said matrix component, and iii) at least one bioceramic or bioglass reinforcing component as a bony ongrowth agent having coarse particles and mixed with said matrix component, the diameter of the resorbable polymeric reinforcing component being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component, said composite material further having increased mechanical strength and ductility.